### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	) ) )	MDL No. 1456
	)	Master File No. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: (All Actions)	)	Judge Patti B. Saris
	)	

# DEFENDANTS JOHNSON & JOHNSON, CENTOCOR, ORTHO BIOTECH, JANSSEN AND MCNEIL-PPC'S SUPPLEMENTAL MEMORANDUM IN SUPPORT OF DEFENDANTS' PROPOSED CASE MANAGEMENT ORDER NO. 10

Defendants Johnson & Johnson ("J&J"), Centocor, Inc. ("Centocor"), Janssen

Pharmaceutica Products L.P. ("Janssen"), Ortho Biotech Products L.P. ("OBP"), and McNeil
PPC ("McNeil") (collectively, the "J&J defendants"), hereby submit this supplemental

memorandum in opposition to the proposed Case Management Order submitted by Plaintiffs on

March 12, 2004 and in further support of Defendants' Proposed Case Management Order.

### BACKGROUND

At the March 8, 2004 status conference, the Court directed the parties to develop a discovery plan that provided for a test case consisting of five companies, as a way of having a "trial balloon." *See* March 8, 2004 Status Conference Transcript (Tr.), relevant pages of which are attached as Exhibit 1, at 14. The Court envisioned that a class would be certified for each company, reasoning that each company took a different approach to drug pricing and marketing. Tr. 11, 29.

The Court further suggested that discovery proceed against the five companies chosen with respect to every drug manufactured by those companies and named in the AMCC Appendix A. Tr. 11-13, 17. The Court directed that this test case track involving five companies be completed within about a year. Tr. 30, 46.

Plaintiffs' proposed Case Management Order distorts the court's directive.

Instead of the five companies specified by the Court, Plaintiffs name as Phase 1 defendants

fourteen separate companies with one hundred and thirty six drugs at issue, and demand

production of all responsive documents on all such drugs within ninety days of service of

document requests. Plaintiffs seek to accomplish this by naming five company "groups,"

ignoring the fact that those groups include independent companies with separate and contrasting

management and policies.

Plaintiffs' approach is particularly egregious with respect to the "Johnson & Johnson Group," which consists of seven separate and independently managed companies with a total of thirty-six drugs at issue. Johnson & Johnson is a holding company for a broad, diverse number of operating companies engaged in a wide variety of health care businesses, including the sale of medical and diagnostic devices, consumer over-the-counter healthcare products, professional healthcare products and prescription drugs. The seven J&J Group companies at issue are disparate companies, each of which is engaged in the research, development and sale of prescription drugs.

Plaintiffs name J&J, Janssen, OBP, McNeil, and Centocor as defendants within the Johnson & Johnson group. See Amended Master Consolidated Complaint ("AMCC") at ¶100-104. The drugs at issue that Plaintiffs ascribe to McNeil in AMCC Appendix A, however, are in fact manufactured by at least three different and independent J&J operating companies: McNeil, Ortho-McNeil Pharmaceutical ("OMP"), and Ortho Neutrogena. See Declaration of Robert Spurr, Vice President of National Accounts at OMP attached as Exhibit 5 ¶ 6-10. The J&J defendants reserve the right to seek relief from the court in relation to all drugs that are not manufactured by a named defendant.

The adjudication of Plaintiffs' claims for those myriad companies and drugs would impose on the J&J defendants an inordinate burden that simply cannot be met within the time frame contemplated for Phase I of this matter.

### ARGUMENT

It is inaccurate to construe and inappropriate to treat J&J and its named operating companies as a single entity for the purposes of expedited adjudication of this matter. Plaintiffs' proposal to pursue expedited proceedings simultaneously against all the J&J-related companies is inequitable, contrary to the Court's proposal, and simply unworkable.

### I. J&J and Its Operating Companies are Distinct Corporate Entities

By designating the entire "Johnson & Johnson Group" for Phase I expedited litigation, Plaintiffs ignore corporate reality and contravene this Court's stated rationale for setting up a discrete and manageable test case involving one class per company.

At the March 8 status conference, the Court stated that a separate class for each defendant company was likely necessary because "each defendant does it [pricing, marketing] a little differently." Tr. 29. This observation hits the nail on the head with respect to the complex and divergent pricing and marketing practices of each separate J&J-related company.

J&J itself is a holding company that sells no products and has a distinct corporate identity from every operating company. *See* Declaration of Thomas J. Spellman III, Assistant Secretary of J&J attached as Exhibit 2 ("Spellman Dec.") at ¶¶ 2-6. Those operating companies each have their own independent boards of directors, typically rely on funding generated from their own operations, and have their own officers responsible for their business decisions.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> See Declaration of Tom Middleton, Executive Director of Managed Care at Janssen attached as Exhibit 3 ("Middleton Dec."), at ¶¶ 3-5; Declaration of William Pearson, Vice President the Oncology and Strategic Customer Group at OBP attached as Exhibit 4 ("Pearson Dec."), at ¶¶ 3-5; Declaration of Robert Spurr, Vice President of National Accounts at OMP attached as Exhibit 5 ("Spurr Dec."), at ¶¶ 3-

The result is that the operating companies price, market and sell very different products in very different ways. For example, Centocor does not provide any discounts or rebates to health care providers, retail pharmacies, or Pharmacy Benefits Managers ("PBMs") on its only product at issue, Remicade, which is a Medicare Part B drug. *See* Hoffman Dec. at ¶ 6, 8. By contrast, OBP does provide discounts and rebates to health care providers, retail pharmacies and PBMs on its only product at issue, Procrit, which also is a Medicare Part B drug. *See* Pearson Dec. at ¶ 6, 8. Meanwhile, OMP and Janssen are in the case for drugs that are *not* covered by Medicare Part B, that are sold primarily through retail pharmacies, and for which the companies offer drug-specific incentives. *See* Spurr Dec. at ¶ 8, 13; Middleton Dec. at ¶ 6, 9. Each J&J-related company determines the incentives to offer on its drugs without referring to or relying on the discounting or rebate practices of the other operating companies. *See* Middleton Dec. at ¶ 9; Pearson Dec. at ¶ 8; Spurr Dec. at ¶ 13; and Hoffman Dec. at ¶ 8. Obviously, the issues facing the companies, and therefore their policies and practices, differ dramatically.

The differences between the companies also are reflected in the varying percentage differences between the published AWPs and list prices for their drugs. The published AWP for Centocor's Remicade is 30% above the published list price (Hoffman Dec. at ¶ 7); the published AWP for OBP's Procrit is 20% above the published list price (Pearson Dec. at ¶ 7); and the published AWPs for the numerous drugs sold by Janssen and OMP are either 20% or 25% above the published list price, depending on the practice of the price reporting service being considered. (Middleton Dec. at ¶ 8; Spurr Dec. at ¶ 12).

Accordingly, the "Johnson & Johnson Group" cannot be collapsed into and treated as one homogenous entity for the purposes of expedited proceedings. Plaintiffs are

<sup>5;</sup> and Declaration of John Hoffman, Executive Director of Strategic Customer Relations at Centocor attached as Exhibit 6 ("Hoffman Dec."), at ¶¶ 3-5.

demanding an extraordinary volume of sales, marketing, and pricing documents from what in truth are seven different sources that likely will provide at least seven sets of answers to and positions on many relevant questions. There is no reason to treat these entities as anything but separate companies under the reasoning laid out by the Court as well as the law pertaining to corporate separateness. *See*, *e.g.*, *Russell v. Enterprise Rent-A-Car Co. of Rhode Island*, 160 F. Supp. 2d 239, 251 (D.R.I. 2001) ("Courts are hesitant to disregard the independent corporate structure between a parent corporation and its subsidiaries"); *Velazquez v. P.D.I. Enterprises*, *Inc.*, 141 F. Supp. 2d 189, 193 (D.P.R. 1999) (same); *Schaefer v. Cybergraphic Systems, Inc.*, 886 F. Supp. 921, 924 (D. Mass. 1994) (same).

### II. Plaintiffs' Proposed Schedule Is Unworkable

Plaintiffs' proposed approach also places a tremendous and disproportionate burden on the J&J-related companies that will be all but impossible to meet. Plaintiffs' proposed CMO demands that the J&J defendants produce all responsive documents on thirty-six drugs within ninety days of the service of document requests and complete all fact discovery on the drugs by January 21, 2005, shortly after the completion of Class Certification briefing. This schedule is unworkable.

The sheer volume of documents associated with thirty-six drugs – and the effort and expense associated with their collection, processing and production in this compressed time frame – is illustrated by the efforts to date of J&J operating company Centocor to respond to Plaintiffs' discovery requests regarding just one drug, Remicade. So far, Centocor's attorneys have invested approximately 9000 hours to interview some fifty Centocor employees, to identify, collect and review nearly one million pages of documents, and to produce the responsive, non-privileged documents to Plaintiffs. *See* Declaration of Andrew D. Schau attached as Ex. 7

("Schau Dec."), at ¶¶ 2-3. This effort has involved twenty-one full-time attorneys and eight temporary attorneys. *Id.* at ¶ 3. The total cost for this endeavor, to-date, has been over \$2.5 million, which includes attorney time, support personnel time and vendor expenses for processing. *Id.* at ¶ 4.

This expensive, year-long and continuing effort by Centocor's corporate staff and outside counsel related to only *one* drug, Remicade. Plaintiffs' proposed CMO calls for J&J's production of discovery related to *thirty-six* drugs, within ninety days of receiving document requests, with all fact discovery on the drugs to be completed in less than a year. Considering the time and expense associated with production of discovery related just to Remicade (not to mention the formidable number of documents that had to be reviewed in connection therewith), it is evident that it will be virtually impossible for J&J and its related entities to engage in the same effort with respect to thirty-six drugs in the proposed time frame.

#### CONCLUSION

For all the reasons stated above, the J&J defendants respectfully request that the Court approve Defendants' proposed CMO, reject Plaintiffs' proposal, order Plaintiffs to select one J&J-related entity to remain as a Phase 1 defendant, and place the others on the Phase 2 track.

Dated: New York, New York

March 22, 2004

Respectfully Submitted,

By:

Andrew D. Schau (admitted *pro hac vice*) adschau@pbwt.com

auschau@powt.com

Erik Haas (admitted pro hac vice)

ehaas@pbwt.com

PATTERSON, BELKNAP, WEBB & TYLER LLP

1133 Avenue of the Americas

New York, NY 10036-6710

(212) 336-2000

Attorneys for defendants Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutica Products L.P., Ortho Biotech Products L.P., and McNeil-PPC.

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2		MDL NO. 1456
3		CA NO. 01-12257-PBS
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6		IN RE: AVERAGE WHOLESALE PRICE
7		PHARMACEUTICAL LITIGATION
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10	BEFORE: T	he Honorable Patti B. Saris
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12		STATUS CONFERENCE
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15	J	ohn Joseph Moakley United States Courthouse Courtroom No. 13
16		One Courthouse Way Boston, MA 02210
17		Monday, March 8, 2004 3:07 P.M.
18		3.07 F.M.
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20		Cheryl Dahlstrom Official Court Reporter
21		United States District Court 595 Main Street, Room 514
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a class action, it would be company by company, not some 2 massive thing that I couldn't begin to control or manage. Each company is different. Each one may have different 3 practices. I could decide the juridical linkage issue within 4 5 a company. 6 So I was somewhat thinking in terms of your picking 7 the companies you were the furthest along in on the basic 8 AWP -- I know there are several models at this point -- and 9 just see whether those issues fly. 10 MR. BERMAN: Well, we thought about that. There's a 11 couple issues why we didn't go down that route. Number 1, we've been waiting for two years now to get at some of the 12 13 defendants. We haven't got any discovery on generics. We 14 haven't gotten even basic governmental documents from some. THE COURT: I'm talking about the initial ones, the 15 16 initial ones when we entered this fray. I've expanded it to 17 Multisource, so you'll get those documents. You should be largely through the Medicare Part B documents anyway for the 18 19 initial ones. 20 MR. BERMAN: The initial ones are just a small subset 21 of the defendants that have Part B reimbursable drugs. It's 22 six, seven drugs. That's all that were at issue, that 23 discovery was permitted to go forth on. THE COURT: Which companies are those? 24 25 MR. BERMAN: That would be GSK, BMS, J & J, Astra --

I think there's a couple more -- Immunex. I think there's one 2 other. 3 THE COURT: Why wouldn't that be a discrete world? 4 Let's say there's one more. Why wouldn't that be a discrete 5 world? You've got government investigation documents. That's why you got to them initially. You'll have a brief additional 7 period of time to figure out Multisource. I'm not talking about the Together Rx. And then we'll set up class 9 certification and a summary judgment schedule, and I will be 10 able to -- those are your prime cases. That's where you led 11 off with those people. 12 MR. BERMAN: Not necessarily our prime cases. That's 13 not necessarily true. For example, on some of those 14 defendants, we weren't -- there are many defendants we weren't 15 allowed to proceed on because we didn't have the right facts 16 first go-round. 17 THE COURT: Maybe you don't take the initial six. 18 But take my theory for a minute. You take your top five 19 companies. You take, you know, whatever it is and we focus on those companies and we see -- let's say your five best 20 21 theories. Maybe I gave the defendants their best as to why it 22 doesn't. And then I could look across the country -- not the 23 country, although that's true, too -- across a company, see 24 what's going on here. Maybe your three best, their three best 25 companies, and do the class certification thing. And then

1 everybody in the middle will know where the legal lay of the land is. There will probably be an appeal at some point, I'm 3 assuming, on the class certification. People will want to 4 test the theory. We'll have a universe. MR. BERMAN: Are you talking about with respect to 5 6 the best five companies? 7 THE COURT: From your point of view, and maybe the 8 best five from theirs. MR. BERMAN: That we proceed on all drugs, all 9 classes on those companies? 10 11 THE COURT: Maybe that might be too much for me or 12 even you. Maybe you want to take the best three companies. MR. BERMAN: One of our concerns is, in our proposal 13 that we tried to do, whatever way we come out, is that we have 14 a cross-section so that -- you mention the theory -- so that 15 16 we get the generics. We get the Part B. We get everything 17 covered so we get some answers going forward. THE COURT: Fair enough. There must be a few 18 companies that pick that up, right? 19 20 MR. BERMAN: We'll be glad to pick some companies. But the only down side that we see to that is -- we went back 21 and forth on this internally, whether we should try that 22 approach -- is that then you have a whole group of defendants 23 that are out there who have been given -- I don't know how 24 long this process will take for the five companies. But let's 25

1 say it's seven, eight, nine months down the road before we get 2 to resolution points, which is probably realistic. Then these other companies have basically sat around 3 4 for two or three years waiting. We get to resolution points, and then we're going to be in a situation, most likely with 5 6 respect to those companies, where they're going to say, hey, 7 you haven't seen my stuff. I'm not like those other companies. Then we start all over. 8 9 THE COURT: That may be, but the truth is --10 MR. BERMAN: There were two, three years. 11 THE COURT: You're more experienced than I am. I have never had a case of this magnitude. I would imagine it's 12 one of the largest cases most people in this room have dealt 13 with. We've got to come up with a way of having a trial 14 15 balloon. I don't think a few drugs here -- taking every 16 company across the board is going to do that because, for one 17 thing, it won't work for class certification. I won't be able 18 to decide the juridical linkage issue. I think there's good 19 20 case law for you for it. I've got to decide whether they're typical. I won't be able to certify a class involving every 21 drug in a company. It will postpone almost indefinitely the 22 class certification issue. 23 MR. BERMAN: We're asking you in our proposal to 24 certify just a few drugs for each company. I don't think it's 25

1 buying directly --2 THE COURT: By "charge-back," you mean a rebate? MR. BERMAN: They get money, rebate. They're called 3 4 in the industry "charge-backs." Once we get going on discovery, we think we're going 5 6 to be able to say, okay, for all the four drugs in this 7 company that are issued, this is how they do it. It's a 8 common-wide practice. 9 THE COURT: Why wouldn't it make sense to take all 10 the drugs from that company and do the company? 11 MR. BERMAN: We could do it that way, but -- I 12 understand your concern. We want to keep all the defendants 13 moving forward --THE COURT: All right. 14 MR. BERMAN: -- toward resolution. And our concern 15 16 with your way is, then we've got eighteen just sitting out 17 there. We've got to start all over again. 18 THE COURT: What if you were to do two tracks. You were to pick two, you know, what you think you have the best 19 case, and they take two that they think is the best. You've 20 got teams of lawyers. You just put the other ones on a slower 21 22 track. 23 MR. BERMAN: When you say we take two, two 24 defendants? 25 THE COURT: Well, you take your best two, the ones

1 might be a better way to go. MR. SOBOL: In this situation, we have to all be flexible. I just want you to be mindful --3 THE COURT: It would be better --MR. SOBOL: -- the population of people who have been 5 6 affected by the high price of drugs that relates to AWP is an 7 issue that has been looked at time and time again. 8 THE COURT: Has anyone done multiple defendant 9 classes? MR. SOBOL: No. This is the only multiple defendant. 10 THE COURT: I am thinking of going defendant by 11 12 defendant mostly because I'm finding how complex this is. My 13 guess is each defendant does it a little differently. You need to think about it that way, both in terms of relief and 14 15 in terms of manageability and typicality and all that kind of 16 thing. 17 You can persuade me contrary, I suppose, but my 18 initial instinct is I'm going to have to do it that way. 19 That's why I was thinking in terms of resolving some 20 companies. 21 How many would you think would make sense if we did, you know, some companies sort of on a fast track and the 22 others -- you know, we have so many lawyers involved. I can't 23 believe we can't do the others on a slower track. MR. BERMAN: We've been talking while --25

THE COURT: Sure. 1 2 MR. BERMAN: -- you've been talking to the defendants. We think that if your Honor wants to go with this 3 4 fast-track approach, that we'd like to do it for five companies. 5 6 THE COURT: That might be feasible. 7 MR. BERMAN: But we would want the other companies to be on what we would call the average or slow track, being that 8 we're starting the discovery process. You know, there's basic 9 productions going on on a slower level. So we don't have to 10 11 wait eight or nine months and then start everything up. THE COURT: I understand that. There's a track for 12 13 the five. And I can move relatively rapidly and hopefully have a case either to try or to go on appeal within a year or 14 15 something with the five. And then the others will not be 16 starting from scratch, but they will be chugging along either 17 for settlement purposes, if that's possible, or I'll just set 18 sort of a second cutoff. We could go five by five if we need 19 to. MR. BERMAN: I'm not sure either one of us will live 20 21 long enough. THE COURT: When I got the 25 motions to dismiss, by 22 the time I went through the massive ones, I need to focus on 2.3 it company by company and really give everybody -- each 24 25 company a focused attention.

1 court. A list of who the companies are and what their 2 proposal is and see if we can't come up with a plan. THE COURT: All right. I don't care. They can do 3 both. By the 22nd, you'll come up with one if you haven't 4 agreed on one. If you can agree, that's great. 5 I don't want this case to be my judicial career. I 6 7 do think -- I'm trying to get some more resources next year for myself because it's just -- I've got a full case load on 8 top of it. They don't take you off the draw or anything. I'm 9 trying to at least get us in a position where I can make most 10 of the serious decisions by the end of -- what I would call 11 the end of the next clerkship year, not this summer but a year 12 13 from this summer. And I think that's doable. I actually do think we can get through a lot of that. And that's what I'm 14 going to be thinking about. With the judicial budget the way 15 it is, I think I can get an extra law clerk for next year, but 16 I'm not sure I can for the following year. It's year to year. 17 If I can wrap up key pieces of this within a year, I think 18 19 everyone will be happy. 20 I think it's appropriate at some point to find a 21 vehicle to appeal, see what the First Circuit's feel is for 22 it. And, hopefully, I mean, Congress, as you've all pointed out to me, as well as the Secretary of Health and Human 23 Services, is interested. There may be a way, if we keep it 24 25 moving, of reaching some resolution in all of this.

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	:	MDL NO. 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris
	:	DECLARATION OF THOMAS J. SPELLMAN III
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### I, THOMAS J. SPELLMAN III declare as follows:

- 1. I am an Assistant Secretary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. I am familiar with the matters set forth herein and submit this affidavit in support of the Johnson & Johnson defendants' Proposed Case Management Order Regarding Phased Discovery. If called to testify, I could testify competently as to the matters set forth herein.
- 2. Johnson & Johnson is a holding company organized and existing under the laws of the state of New Jersey, with its principal place of business in New Brunswick, New Jersey. Johnson & Johnson holds shares of companies, directly or indirectly, that provide health care products and services, including the companies Centocor, Inc., Ortho Biotech Products L.P., Janssen Pharmaceutica Products L.P., McNeil-PPC, Inc. and Ortho-McNeil Pharmaceutical, Inc. (collectively, the "operating companies").
- 3. The operating companies do not operate, or do business, under the Johnson & Johnson name. Similarly, Johnson & Johnson does not operate, or do business, under the operating companies' names. Johnson & Johnson and each of the operating companies are separate and distinct legal entities and each observe all corporate formalities relating to their separate existences.
- 4. Johnson & Johnson and each of the operating companies manage and operate their own day-to-day business activities independently of each other. Johnson & Johnson and the operating companies each maintain their own independent boards of directors and officers who are primarily responsible for their business.
- 5. Johnson & Johnson does not manufacture, market or sell any products. Johnson & Johnson does not employ personnel to manufacture, market or sell drugs, and has not employed personnel to manufacture, market or sell the operating companies' pharmaceutical products. On information and belief, the operating companies each have their own manufacturing, marketing and sales personnel who perform those functions.
- 6. Upon information and belief, the operating companies each independently develop their marketing, sales and pricing plans for their drugs.

I declare under penalty of perjury that the foregoing is true and correct.

THOMAS J. SPELLMAN III

Executed on this 18th day of March 2004

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	: : : :	MDL NO. 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris
	: : : : X	DECLARATION OF TOM MIDDLETON

#### I Tom Middleton declare as follows:

- 1. I am Executive Director of Managed Care at Janssen Pharmaceutica Products L.P. ("Janssen"). I am fully familiar with the matters set forth herein and submit this affidavit in support of the Johnson & Johnson defendants' Proposed Case Management Order Regarding Phased Discovery. If called to testify, I could testify competently as to the matters set forth herein.
- 2. Janssen is a wholly-owned subsidiary of Johnson & Johnson. I have been advised that other subsidiaries of Johnson & Johnson involved in this litigation include Centocor, Inc., Ortho Biotech Products L.P., and Ortho-McNeil Pharmaceutical, Inc. (collectively, the "operating companies").
- 3. Janssen does not operate or conduct any business under the Johnson & Johnson name. Similarly, upon information and belief, Johnson & Johnson does not operate or conduct any business under Janssen's name. Johnson & Johnson and Janssen are separate and distinct legal entities and each observes all corporate formalities relating to their respective separate existences.
- 4. Janssen manages and operates its day-to-day business activities independently of Johnson & Johnson and the other operating companies. Janssen maintains an independent board of directors and Janssen's own officers are primarily responsible for making its business decisions.
- 5. The funding for Janssen's business comes from its own operations. Thus, Janssen relies on its own resources to develop and market its products. Janssen pays the salaries of its personnel and bears its own expenses.
- 6. I have been advised that plaintiffs have named Janssen as a defendant in this action solely in connection with the pricing and marketing of its drugs Aciphex, Risperdal, Reiminyl, Sporanox, and Duragesic (the "Janssen drugs"). None of the Janssen drugs are infusion or injectable drugs, and none are reimbursed under Medicare Part B.

- 7. Janssen personnel develop and are responsible for the pricing, marketing and sales plans for the Janssen drugs. The only exception is Aciphex, which is co-marketed with Esai Inc., a company that is not related to Johnson & Johnson or its operating companies.
- 8. Until March 2002, the published AWPs for the Janssen drugs were 120% of the published list prices. Starting in March 2002, FirstDataBank independently revised AWPs for the Janssen drugs to 125% of the published list prices (without consultation with or direction from Janssen). RedBook continues to report AWPs for the Janssen drugs at 120% of the published list prices.
- 9. Janssen does not provide discounts or rebates to persons or entities administering or dispensing drugs, e.g., physicians and retail pharmacies. Janssen provides discounts and rebates to Pharmaceutical Benefit Managers and to non-governmental entities that make reimbursement for the costs of the Janssen drugs, e.g., managed care entities. These discounts and rebates differ from drug to drug. Janssen does not refer to or rely on the discounting or rebate practices of the other operating companies in determining the incentives to offer on the sale of Janssen drugs.

I declare under penalty of perjury that the foregoing is true and correct.

TOM MIDDLETON

Willeton

Executed on this 17<sup>h</sup> day of March 2004

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	:	MDL NO. 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris
	:	DECLARATION OF WILLIAM PEARSON
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### I William Pearson declare as follows:

- 1. I am Vice President of the Oncology Franchise and Strategic Customer Group at Ortho Biotech Products L.P. ("OBP"). I am fully familiar with the matters set forth herein and submit this affidavit in support of the Johnson & Johnson defendants' Proposed Case Management Order Regarding Phased Discovery. If called to testify, I could testify competently as to the matters set forth herein.
- 2. OBP is a wholly-owned subsidiary of Johnson & Johnson. I have been advised that other subsidiaries of Johnson & Johnson involved in this litigation include Centocor, Inc., Janssen Pharmaceutica Products L.P., and Ortho-McNeil Pharmaceutical, Inc. (collectively, the "operating companies").
- 3. OBP does not operate or conduct any business under the Johnson & Johnson name. Similarly, upon information and belief, Johnson & Johnson does not operate or conduct any business under OBP's name. Johnson & Johnson and OBP are separate and distinct legal entities and each observes all corporate formalities relating to their respective separate existences.
- 4. OBP manages and operates its day-to-day business activities independently of Johnson & Johnson and the other operating companies. OBP maintains an independent board of directors and OBP's own officers are primarily responsible for making its business decisions.
- 5. The funding for OBP's business comes from its own operations. Thus, OBP relies on its own resources to develop and market its products. OBP pays the salaries of its personnel and bears its own expenses.
- 6. I have been advised that plaintiffs have named OBP as a defendant in this action solely in connection with the pricing and marketing of its drug Procrit. Procrit is an injectable drug that is reimbursed under Medicare Part B. OBP personnel develop and are responsible for the pricing, marketing and sales plans for Procrit.
- 7. The published AWP for Procrit has always been 120% of its published list price.

8. OBP has provided discounts and rebates on Procrit to persons or entities administering or dispensing drugs, e.g., doctors, hospitals and retail pharmacies. OBP has also provided discounts and rebates to Pharmacy Benefits Managers and to non-governmental entities that reimburse physicians for the costs of Procrit, e.g., managed care entities. OBP does not refer to or rely on the discounting or rebate practices of the other operating companies in determining the incentives to offer on the sale of its drugs.

I declare under penalty of perjury that the foregoing is true and correct.

William PEARSON

Executed on this 17<sup>h</sup> day of March 2004

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	: : : : : :	MDL NO. 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris  DECLARATION OF ROBERT SPURR

### I Robert Spurr declare as follows:

- 1. I am Vice President of National Accounts at Ortho-McNeil Pharmaceutical ("OMP"). I am fully familiar with the matters set forth herein and submit this affidavit in support of the Johnson & Johnson defendants' Proposed Case Management Order Regarding Phased Discovery. If called to testify, I could testify competently as to the matters set forth herein.
- 2. OMP is a wholly-owned subsidiary of Johnson & Johnson. I have been advised that other subsidiaries of Johnson & Johnson involved in this litigation include Centocor, Inc., Janssen Pharmaceutica Products L.P., and Ortho Biotech Products L.P. (collectively, the "operating companies").
- 3. OMP does not operate or conduct any business under the Johnson & Johnson name. Similarly, upon information and belief, Johnson & Johnson does not operate or conduct any business under OMP's name. Johnson & Johnson and OMP are separate and distinct legal entities and each observes all corporate formalities relating to their respective separate existences.
- 4. OMP manages and operates its day-to-day business activities independently of Johnson & Johnson and the other operating companies. OMP maintains an independent board of directors and OMP's own officers are primarily responsible for making its business decisions.
- 5. The funding for OMP's business comes from its own operations. Thus, OMP relies on its own resources to develop and market its products. OMP pays the salaries of its personnel and bears its own expenses.
- 6. I have been advised that OMP is not a named defendant in the Amended Master Consolidated Class Action Complaint ("AMCC"). However, OMP manufactures, markets or sells the majority of the drugs ascribed to McNeil-PPC by plaintiffs in AMCC Appendix A. McNeil-PPC is related to OMP only in that it also is a Johnson & Johnson subsidiary.

- 7. The drugs ascribed to McNeil-PPC by plaintiffs in AMCC Appendix A that are or were in fact manufactured, marketed or sold by OMP are: Bicitra, Elmiron, Floxin, Haldol, Haldol Decanoate, Levaquin, Monistat, Mycelex, Pancrease, Parafon Fort, Polycitra, Regranex, Terazol, Testoderm, Tolectin, Topamax, Tylox, Tylenol with codeine, Ultracet, Ultram, Urispas, and Vascor (the "OMP drugs.").
- 8. None of the OMP drugs at issue in this litigation are injectable or infusion drugs, and none are reimbursed under Medicare Part B.
- 9. Upon information and belief, other drugs ascribed to McNeil-PPC by plaintiffs in AMCC Appendix A are in fact manufactured, marketed or sold by Ortho Neutrogena, another independent Johnson & Johnson subsidiary. Those drugs include Erycette, Grifulvin, Renova, Retin-A, Retin-A Micro, and Spectazole.
- 10. Upon information and belief, drugs that are in fact manufactured, marketed or sold by McNeil-PPC as alleged by plaintiffs in AMCC Appendix A include Flexeril.
- 11. OMP personnel develop and are responsible for the pricing, marketing and sales plans for the OMP drugs.
- 12. Until March 2002, the published AWPs for the OMP drugs were 120% of the published list price. Starting in March 2002, FirstDataBank independently revised the AWPs for the OMP drugs to 125% of the published list price (without consultation or direction from OMP). RedBook continues to report AWPs for the OMP drugs at 120% of the published list price.
- pharmacies, with the limited exception of a stocking incentive to retail pharmacies in the case of new product launches. OMP does provide discounts and rebates to Pharmacy Benefits Managers and to non-governmental entities that make reimbursement for the costs of the OMP drugs, *e.g.*, managed care entities. These discounts and rebates differ from drug to drug. OMP does not refer to or rely on the discounting or rebate practices of the other operating companies in determining the incentives to offer on the sale of its drugs.

I declare under penalty of perjury that the foregoing is true and correct.

ROBERT SPURR

Executed on this 17<sup>h</sup> day of March 2004

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

ه جو ج گ اللي ن با با بد بده به مارات سيف بده به به به ۱۹۸۹ کرد. م سود به بدن ده ده و سود به ندار به بدن در سود و سود به بازی با بدن در سود و سود به بازی بازی بازی بازی بازی بازی بازی بازی	· X	
In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	:	MDL NO. 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris
	: : : • X	DECLARATION OF JOHN HOFFMAN

### I John Hoffman declare as follows:

- 1. I am Executive Director of Strategic Customer Relations at Centocor, Inc. ("Centocor"). I am fully familiar with the matters set forth herein and submit this affidavit in support of the Johnson & Johnson defendants' Proposed Case Management Order Regarding Phased Discovery. If called to testify, I could testify competently as to the matters set forth herein.
- 2. Centocor is a wholly-owned subsidiary of Johnson & Johnson. I have been advised that other subsidiaries of Johnson & Johnson involved in this litigation include Ortho-Biotech Products L.P., Janssen Pharmaceutica Products L.P., and Ortho-McNeil Pharmaceutical, Inc. (collectively, the "operating companies").
- 3. Centocor does not operate or conduct any business under the Johnson & Johnson name. Similarly, upon information and belief, Johnson & Johnson does not operate or conduct any business under Centocor's name. Johnson & Johnson and Centocor are separate and distinct legal entities and each observes all corporate formalities relating to their respective separate existences.
- 4. Centocor manages and operates the bulk of its day-to-day business activities independently of Johnson & Johnson and the other operating companies. Centocor maintains an independent board of directors and Centocor's own officers are primarily responsible for making its business decisions.
- 5. The funding for Centocor's marketing comes from its own operations. Centocor pays the salaries of its personnel and bears its own expenses.
- 6. I have been advised that plaintiffs have named Centocor as a defendant in this action solely in connection with the pricing and marketing of its drug Remicade. Remicade is an infusion drug that is reimbursed under Medicare Part B. Centocor personnel develop and are responsible for the pricing, marketing and sales plans for Remicade.
- 7. The published AWP for Remicade has always been 130% of its published list price.

8. Centocor does not provide discounts or rebates on Remicade to persons or entities administering or dispensing drugs, e.g., physicians, hospitals or retail pharmacies. Centocor also does not provide discounts or rebates to Pharmacy Benefits Managers. Centocor does provide rebates to non-governmental entities that reimburse physicians for their Remicade costs, e.g., managed care entities. Centocor does not refer to or rely on the discounting or rebate practices of the other operating companies in determining the incentives to offer on the sale of its drugs.

I declare under penalty of perjury that the foregoing is true and correct.

JOHN HOFFMAN

Executed on this 17<sup>h</sup> day of March 2004

### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

	X	
In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	: : : : :	MDL NO. 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris
	: : : X	DECLARATION OF ANDREW D. SCHAU

### I Andrew D. Schau declare as follows:

- 1. I am an attorney admitted to practice before the Courts of New York State and am admitted *pro hac vice* in the United States District Court for the District of Massachusetts, and am a member of Patterson, Belknap, Webb & Tyler LLP, attorneys for defendants Johnson & Johnson, Centocor Inc., Janssen Pharmaceutica Products L.P., Ortho Biotech Products L.P., and McNeil PPC (collectively the "J&J defendants"). I submit this declaration in support of the J&J defendants' opposition to the proposed Case Management Order submitted by Plaintiffs on March 12, 2004 and in support of Defendants' Proposed Case Management Order.
- 2. Centocor, Inc. has been subject to discovery for its drug Remicade since the Court's Order dated May 13, 2003. Centocor began producing documents to plaintiffs in October, 2003 and continues to do so on a rolling basis. Responding to plaintiffs' broad discovery demands has been an enormous undertaking involving considerable attorney, support staff and Centocor personnel time.
- 3. The review process and the process of producing responsive, non-privileged documents to the plaintiffs has taken approximately 9,000 attorney hours. Attorneys for Centocor interviewed and collected documents from some fifty Centocor employees and have reviewed or are in the process of reviewing nearly one million pages of documents for relevance and privilege. Twenty-one full-time attorneys and eight temporary attorneys have been involved in this effort.
- 4. To date, these combined efforts, including attorney time, support staff time, and outside vendor expenses, have resulted in charges to Centocor of more \$2.5 million.

I declare under penalty of perjury that the foregoing is true and correct.

ANDREW D. SCHAU

Executed on this 19<sup>h</sup> day of March 2004